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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,617	03/01/2004	RameshBabu Boga	KCX-827 (20129)	8844

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,617	BOGA ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-7,12-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,12-16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 1, 5, 7, 14, 16 and 18 are acknowledged, as well as the cancellation of claims 1-4, 8-11, 17 and 22 – 38.

Currently, claims 1, 5-7, 12-16, and 18-21 are pending and under examination.

Withdrawn Objections and Rejections

The previous objection to claim 16 is withdrawn in view of Applicant's amendments filed February 19, 2008.

All previous rejections of the claims under 35 U.S.C. 112, second paragraph, are withdrawn in view of Applicant's amendments filed February 19, 2008.

All previous rejections of the claims under 35 U.S.C. 102 and 103 are withdrawn in view of Applicant's amendments and arguments filed February 19, 2008.

Response to Arguments

Applicant's arguments, see p5-6, filed February 19, 2008, with respect to the rejection(s) of the claim(s) under 35 U.S.C. 102 and 103 have been fully considered and are persuasive. Applicant argues that the Harris et al. reference (US 5,599,913), which was applied in both the 35 U.S.C 102(b) and 103(a) rejections, fails to teach a chemichromic dye comprising a triarylmethane, which was previous recited in dependant claim 4 and is now incorporated into independent claim 1. After further review of the reference, this argument has been found to be persuasive. Therefore, the

rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of MacDonald et al. (US 2005/0085739).

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 – 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 14 and 15 recite the term "said fluidic medium," which lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5 – 7, 12 – 14, 16 and 18 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Miller et al. (US 7,014,816) and MacDonald et al. (US 2005/0085739).

Daniels et al. teach an immunochromatographic test strip (assay device) for detecting the presence or absence of an analyte within a test sample, said test strip comprising a porous membrane that is in fluid communication with a detection reagent (probes) conjugated with a specific binding member for the analyte, said porous membrane defining:

a capture region (second detection zone) within which a capture reagent is immobilized to bind to said detection reagent or complexes thereof to generate a detectable (detection) signal, wherein the amount of analyte in the test sample is proportional to the intensity of the detectable signal (see Figures 1 and 3; and paragraphs [0108]-[0120], [0133], [0201]-[0203], and [0232]-[0236]).

Daniels et al. teach the use of their test strip to detect various analytes, including bacteria, viruses and other microorganisms, such as those found in biological fluids, water or food stuffs (see paragraphs [0094], [0095], and [0232]-[0236]). However, Daniels et al. fail to teach the detection of amines, wherein the porous membrane includes a first detection zone that comprises an immobilized chemichromic dye in the form of a triarylmethane dye, said dye capable of undergoing a detectable color change upon reaction with one or more amines.

Miller et al. teach a device for detecting amines in a test sample, wherein the device comprises a substrate and a polymeric matrix that contains an indicator compound. The indicator compound can comprise various dyes that are capable of undergoing a detectable color change upon reaction with one or more amines. Amines represent volatile bases that are generated by food decomposition, therefore, the device provides an effective means to indicate the presence of an unwanted biological agent, such as bacteria or fungi, in a sample, particularly a food sample, by colorimetric detection of amines (see Figures; and column 1, lines 20-61; column 3, lines 39-50; column 4, lines 4-49; column 5, lines 8-34; and column 6, lines 5-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device for detecting analytes of Daniels et al. a detection zone that comprises a colorimetric reagent that undergoes a color change in the presence of amines as taught by Miller et al. because Miller et al. teach that a device that comprises an indicator dye that undergoes a color change in the presence of amines provides an effective means to indicate the presence of an unwanted biological agent, such as bacteria or fungi, in a sample, particularly a food sample, by colorimetric detection of amines.

However, Miller et al. fail to teach that the indicator dye specifically comprises triarylmethane, including those recited in Applicant's claims 5-7 and 18-20.

MacDonald et al. teach a device for indicating bad breath, wherein the device comprises a substrate with an applied visual indicating agent, which undergoes a color change in the presence of sulfur or ammonia. The visual indicating agent can comprise

a variety of chemical agents. However, the visual indicating agent preferably comprises a triarylmethane in the form of alpha-naphtholbenzein or naphthochrome, which are dyes well known for changing color in the presence of ammonia, amines, diamines, or polyamines (see Abstract; and paragraphs [0013], [0015], and [0033]-[0037]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the indicator dye of the device of Daniels et al. and Miller et al. with a triarylmethane, including those recited in Applicant's claims 5-7 and 18-20, as taught by MacDonald et al. because MacDonald et al. teach the benefit of visual indicating agents that comprise various chemical compositions, including triarylmethanes, particularly the various triarylmethane recited in Applicant's claims 5 – 7 and 18 – 20, because these visual indicating agents comprise dyes that are well known for changing color in the presence of amines.

Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Miller et al. (US 7,014,816) and MacDonald et al. (US 2005/0085739), as applied above, and further in view of Lawrence et al. (US 6,099,801).

Daniels et al. teach the inclusion of a control region downstream from said capture region, however, Daniels et al., as well as Miller et al. and MacDonald et al., fail to teach that the control zone contains a chemichromic dye.

Lawrence et al. teach a pH and amine test element that is useful in the diagnosis of vaginal infections. The test element contains a test section that is capable of

detecting volatile amines in a test sample, wherein the amine test section contains an indicator that undergoes a detectable color change in the presence of a volatile amine. The amine test section also contains a second indicator that functions as a control and undergoes a detectable color change regardless of the presence of volatile amines in the test sample. The inclusion of a control that contains a color-changing indicator in both the pH and amine test sections of the test element is useful in order to assure that the indicator is not malfunctioning for reasons such as manufacturing error in the device, and that the device has been exposed to sufficient sample to produce a reading if the sample is indeed positive (see Figures; Abstract; column 4, lines 5-25 and lines 64-67; column 5, lines 1-17; column 9, lines 54-57; column 10, lines 20-27; column 11, lines 22-54; and column 12, lines 7-27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Daniels et al., Miller et al. and MacDonald et al. a control zone with a color-changing (chemichromic) dye as taught by Lawrence et al. because Lawrence et al. teach the benefit of including a control region with a second color-changing indicator, wherein a test area contains a first color-changing indictor, in order to assure that the indicator is not malfunctioning for reasons such as manufacturing error in the device, and that the device has been exposed to sufficient sample to produce a reading if the sample is indeed positive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641